**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

**OFFICE OF**
**PREVENTION, PESTICIDES AND**
**TOXIC SUBSTANCES**

December 17, 2002

**MEMORANDUM**

SUBJECT: EFED response to USDA/APHIS' and The Zinc Phosphide Consortium errors-only comments on the Agency document "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals"

TO: John Pates, Chemical Review Manager
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THRU: Stephanie Irene, Acting Chief
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The Environmental Fate and Effects Division (EFED) has reviewed USDA/APHIS' and The Zinc Phosphide Consortium's (TZPC) "errors-only" response to the Agency document "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals" dated October 3, 2001. Their comments were prepared by C. Bausch, Director, Environmental Services, and K. A. Fagerstone, Coordinator of TZPC. As stated in the Agency's October 23, 2001 cover letter for the assessment, the registrants' 30-day response should address only mathematical, computational, typographic, or other similar errors. Matters of policy, interpretation, or applicability of data will be addressed after the public comment period in accordance with the Agency's reregistration process for pesticides.

In response to error comments by APHIS, TZPC, other rodenticide registrants, and the Rodenticide Registrants Task Force, EFED has made necessary computational and/or typographical corrections. However, EFED notes that many comments relate to policy, interpretation, or applicability of data, and those comments will be addressed along with public comments after the 60-day public-comment period.

1) **Comment:** It should be emphasized that the 10/01 Draft compares the potential hazard rodenticides present to nontarget organisms. The comparisons drawn are almost entirely based on the inherent toxicity of these compounds to test organisms, toxicity estimates that were derived from standardized laboratory experiments. As you are aware, a risk assessment must consider both the potential effects of a compound on an organism in combination with the potential for that organism to be exposed to the compound. The 10/01 Draft should emphasize that regardless of final risk calculations presented in this document, there is no risk if the organism does not come in contact with the compound.

**EFED response:** This has been addressed in the revised document. It is well known that rodenticide baits are formulated to be lethal to rodents and a few other small mammals, and they are not selective to the target species. Although many factors influence which nontarget animals might be exposed to baits, many nontarget organisms are attracted to and consume grain-based baits. Predators and scavengers also feed on rats and mice or other target species, and they are not likely to avoid feeding on those that have eaten rodenticide bait. Thus, rodenticide baits also pose potential secondary risks. EFED believes that when all that available data is considered, the potential for risks to birds and nontarget mammals are well established for some of these rodenticide baits.

The Agency's risk assessment is based on the available data. Registrants have not submitted the data that would be needed to assess the probability of exposure. These data have been outlined in a section on *Uncertainty and Data Needs* in the revised assessment. The methodology used is similar to that used in the Agency's "Comparative Analysis of Acute Risk From Granular Pesticides" (EPA 1992) and "A Comparative Analysis of Ecological Risks from Pesticides and Their Use: Background, Methodology, Case Study" (EPA 1998)[1]; both were reviewed by a FIFRA Scientific Review Panel. Concerning the latter analysis, the Panel noted the many scientific uncertainties in the method, yet agreed that it was a useful screening tool that provides a rough estimate of relative risk. The Panel made a number of helpful suggestions to improve the utility of the method, most of which are included here.

Risk conclusions are presented in tabular and graphical form based on two analyses of the available data. The first is a comparative ranking of the potential risk based on a comparative-analysis model, and the second is a tabular comparative rating of potential risk based on a qualitative "weight-of-evidence" assessment. Quantitative estimates of risk are used in both; however, the "weight-of evidence" assessment includes qualitative assessments of secondary risk based on mortality and other adverse effects reported in laboratory and field studies, operational control programs, and incident reports, as well as toxicokinetic data and residue levels reported in primary consumers. This approach is in concert with EPA's risk-assessment

[1] See December 8-9, 1998 http://www.epa.gov/scipoly/sap/1998/index.htm

guidelines[2], where professional judgement or other qualitative evaluation techniques may be used to rank risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms.

2) **Comment:** Dr. Erickson made an effort to include results of field studies submitted in support of product registrations as well as studies from the open literature. However, we feel that the only information extracted from these reports was information pertaining to negative effects. There is no discussion of studies that did not report negative effects. We realize study results reported in the open literature may omit certain aspects of the results. Consequently, adverse effects may not be reported if it is not pertinent to the objectives of the study. However, studies conducted and submitted for purposes of supporting product registrations must include all occurrences during the study. Therefore, if an adverse effect occurred, it would be reported. It is our feeling that many studies which did not report adverse effects were left out of the 10/01 Draft. It is important that the Agency report and use all of the available data if it is going to report any data at all.

For example, the NWRC conducted a primary hazard study of 39 wild-caught and 32 pen-reared ring-necked pheasants (*Phasianus colchicus*) in California alfalfa fields treated with 2% zinc phosphide treated oat bait. This study was submitted to the EPA to support a product registration (MRID No. 445754-01). However, it is not included in the 10/01 Draft. This exhaustive field study showed no zinc phosphide related effects on either captive-reared pheasants released at the study site or wild pheasants using the stubble field and the adjacent habitat. This study is a perfect example of the difference between toxicity data (high risk to pheasants) versus exposure data (low risk to pheasants). We urge EPA to make these types of distinctions.

**EFED response:** EFED disagrees that only studies reporting negative effects were cited in the risk assessment. In fact, APHIS' own conclusions on the risks of zinc phosphide (Johnson and Fagerstone, 1994, Primary and Secondary Hazards of Zinc Phosphide to Nontarget Wildlife - a Review of the Literature, USDA/APHIS/DWRC Research Report No. 11-55-005.) are quoted in the assessment. The following statements are taken directly from the assessment and demonstrate that the risk assessment presented an accurate balance of results from available reports. APHIS/TZPC's contentions that only negative effects are reported are not supported.

> "Secondary risks appear to be low for zinc phosphide, . . . Zinc phosphide-poisoned prey caused the deaths of only 3 of 77 mammals and none of 19 birds of prey exposed in 15 studies. Some animals regurgitated prey and others refused to consume gastro-

[2] See Guidelines for Ecological Risk Assessment (EPA/630/R-95/002F, 1998) at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460

intestinal tracts. Almost all zinc phosphide detected in the carcass of animals that died from eating bait was in the GIT, likely as undigested bait"

"Only 3 (4%) of 77 test animals (foxes, dogs, ferrets, weasels, domestic cats, mink, mongooses) died after feeding on rodents poisoned with zinc phosphide in 10 studies (Table 23). Some regurgitation of prey was reported in animals that died and in some survivors that consumed GI tracts of poisoned rodents (Evans 1965, Schitoskey 1975, Hill and Carpenter 1982, Tkadlec and Rychnovsky 1990). Some species avoid eating the GI tract or soon learned to avoid them."

"Johnson and Fagerstone (1994) reviewed the primary hazard information for zinc phosphide. They indicate that some birds are repelled by zinc phosphide and others may regurgitate bait. Spotted doves (*Streptopelia chinensis*), for example, were reported to regurgitate treated seeds about 1 hour after ingestion (Hilton et al. 1972, Pank et al. 1972)."

"Other studies also indicate that zinc phosphide bait poses a risk to some birds, but some species may be less susceptible than others."

"All white-fronted geese survived, which the authors attributed to their developing an aversion to bait after ingesting sublethal doses during the first 2 days of exposure."

"Hegdal and Gatz (1977) evaluated hazards to nontarget wildlife from zinc phosphide bait (2% ai) broadcast by ground or air at rates of 5 to 10 lb per acre for vole control in Michigan orchards. About 950 acres were treated in the study area, and intensive carcass searches were made across 672 acres for 2 weeks after treatment. Bird carcasses recovered included 1 blue jay (*Cyanocitta cristata*) and 1 of 5 radio-equipped pheasants. Northern bobwhite were observed, and some were seen feeding on bait, but no carcasses were found."

"Johnson and Fagerstone (1994) reviewed a number of field studies conducted to evaluate primary effects of zinc phosphide on nontarget wildlife for the following uses: prairie dogs, ground squirrels, and jackrabbits on rangeland; California ground squirrels and rats on ditch banks; voles and rats in orchards; and rats in sugarcane. They also note that some information on nontarget hazards has also been gathered for the following uses: voles in alfalfa and muskrats and nutria in wetlands. They conclude that "Although field studies to determine effects of zinc phosphide on nontarget wildlife have generally found no significant effects, under certain circumstances operational zinc phosphide applications have resulted in mortality of nontarget wildlife."

"Zinc phosphide appears to pose minimal secondary risk to predators and scavengers; it is not stored in tissues of primary consumers to the same extent as anticoagulants, but undigested bait in the primary consumer’s GIT may be consumed by a raptor or scavenger."

"Several field tests designed to assess the efficacy of chlorophacinone and zinc phosphide have included nontarget carcass searches as a secondary objective. None found any indications that raptors or avian scavengers were killed from feeding on poisoned target species."

"Based on the laboratory secondary toxicity data, all 6 anticoagulants appear to pose a considerable risk to mammalian predators and scavengers, . . . Risks from zinc phosphide appear to be low for most species, especially those that don't eat stomach contents of their prey."

The pheasant study identified as MRID No. 445754-01 was not cited in the assessment, because it had not been submitted to EFED for review; therefore, EFED had no record of the study. A copy has been obtained from Agency microfiche files and the findings summarized in the revised risk assessment. Regarding statements that other studies submitted to support product registration were not considered, APHIS/TZPC provided no documentation (i.e., MRID numbers) of any other studies submitted to the Agency. EFED had requested many of the unpublished reports cited in Johnson and Fagerstone (1994) from the Information Services Unit of the National Wildlife Research Center. Some of the reports were available but others were not. Of those obtained, some did not even mention nontarget risks (e.g., Ellis et al. 1966); others provided no supporting data while noting that it is doubtful that zinc phosphide is exclusively selective for the target species (e.g., Evans et al. 1970).

3) **Comment:** A toxicity classification system based solely on a compounds inherent toxicity is misleading and the weaknesses of such systems should be explained in detail before they are used. For example, included in the 10/01 Draft is a descriptive language loosely categorizing the toxicity of rodenticides by two organizations, the World Health Organization (WHO) and the Pesticide Action Network (PAN). When describing the toxicity of rodenticides, both organizations use a compound's acute oral toxicity (LD50) to rats and mice. Based solely on the LD50 value, the compounds are ranked as "extremely hazardous" and "highly hazardous" by the WHO or "Bad Actor" by PAN. We object to using inflammatory/unprofessional language such as "Bad Actor" within a regulatory document. It is our belief that such language only serves to mislead the reader. It is a fact that all rodenticides can be hazardous to mammals when used improperly. However, proper use of a product (i.e. following the label directions) significantly reduces or eliminates the hazard by eliminating the risk of exposure.

**EFED response:** The descriptors of the WHO and the PAN were removed from the assessment. However, EFED notes that these descriptors indicate there is widespread concern about the toxicity and potential for adverse effects from zinc phosphide. APHIS/TZPC have provided no documentation to support their assertion that the exposure of nontarget organisms to rodenticide baits and the potential risk can be eliminated, especially from broadcast or other unprotected bait applications. As already noted, rodenticide baits are not selective to the target species and are likely to be eaten by nontarget species.

4) **Comment:** When conducting a risk assessment, the EPA should state what levels of biological organization are targeted for protection (e.g. individual or population). It is our feeling that an individual must be protected only when the population of that organism is small enough to warrant special protection. A species should not have to be listed as threatened or endangered to deserve extra consideration against accidental kills. However, most species are not in need of special protection and many species are so numerous that they are considered pests. Unintentional kills of abundant organisms through the use of rodenticides may have no effect on the existence of the population as a whole. The 10/01 Draft should define when the protection of individuals or populations should be the target of a risk assessment.

**EFED response:** APHIS/TZPC have made statements concerning risks to individuals and populations of nontarget organisms that beg follow-up questions for clarification and documentation for support. Examples of such statements are:

> "*However, most species are not in need of special protection and many species are so numerous that they are considered pests*." and
>
> "*Unintentional kills of abundant organisms through the use of rodenticides may have no effect on the existence of the population as a whole*."

How was this determined? Were population levels monitored before and after treatments? If so, how were they monitored (e.g., telemetry, mark-recapture, etc.). If APHIS/TZPC have such data, why were they not submitted to the Agency? These statements seem to imply that risks to nontarget organisms are of little concern.

5) **Comment:** We agree with the Agency that adverse effects reports should be considered when conducting risk assessments. However, the Agency should make an extra effort to evaluate each incident for accuracy and completeness at the time the incident is entered into the database and prior to using the data. In addition, when using these data each record should be checked to ensure duplicate counting is not occurring. We feel this has become very important with recent implementation of EPA's new 6(a)(2) reporting requirement. The new 6(a)(2) reporting guidelines require reporting incidents when only a minimum amount of information is available. So little information is required that it may result in multiple reports of the same incident and there may not even be enough information to accurately attribute it to a pesticide product. For example, if an incident occurs and "zinc phosphide" is implicated but no specific product is identified, every registrant of zinc phosphide products that becomes aware of the incident is required to report the incident. This could result in more than 15 reports for the same incident.

The Rodenticide Task Force (RTF) conducted an evaluation of rodenticide related incidents. They obtained the data from the EIIS database. Every incident was evaluated independently for completeness and cross-checked to eliminate duplicate records. Their evaluation differed from EPA's evaluation of the data in that fewer incidents could be

directly attributed to pesticides. We feel that the 10/01 Draft did not adequately consider the RTF's evaluation of the incident data.

**EFED response:** Only two of the 258 incidents cited in the assessment were submitted under the 6(a)(2) reporting guidelines, so the duplication of incidents under that reporting has not occurred for the rodenticides. The RRTF's analysis of incidents is based on raw data in the Ecological Incident Information System (EIIS), not on the incident data presented in the risk assessment. Neither the RRTF, APHIS/TZPC, nor any other registrant has identified any duplicate incident reports used in the risk assessment. All registrants and interested parties should address the incident data presented in the risk assessment, not that in the EIIS database.

6) **Comments:** The 10/01 Draft went to great lengths to rebut the RRTF's proposal to set an effects threshold of 0.7 ppm brodifacoum in liver tissue. We feel the EPA brought up significant evidence to set the threshold at a level lower than 0.7 ppm. (However, the document did not propose a new threshold concentration.) We object to the EPA's use of one study when refuting the RTF's threshold. The 10/01 Draft used data obtained from a study with coyotes using diphacinone. This study was conducted by scientists at our National Wildlife Research Center. We feel the results of the study are valid and can be used to assess impacts of diphacinone. However, results obtained while studying diphacinone should not be used when discussing the effects of brodifacoum. The pharmacokinetics of the two compounds are different enough that the comparisons made in the 10/01 Draft are difficult to defend.

**EFED response:** EFED agrees with APHIS/ TZPC that a "toxicity threshold" needs to be established for each of the nine rodenticides. However, we disagree with the RRTF's apparent contention that mortality is the only endpoint of concern. The Agency also regulates pesticides on the potential for adverse sublethal effects, and a data call-in will be issued to address this concern. The reference to the diphacinone study with coyotes has been removed from this section of the assessment.

7) **Comment:** A paragraph in the section "Risk Conclusions" requires correction. In this paragraph you state *"USDA/APHIS, for example, uses a 6-g diphacinone bait pellet for rat control in Hawaii."* This statement is inaccurate. USDA/APHIS is not using this product. It is being used under an experimental use permit by the USGS Biological Survey. The U.S. Fish and Wildlife Service, National Park Service, Department of Defense, and Hawaii Department of Natural Resources strongly support obtaining a state registration for aerial delivery of this product for protecting threatened and endangered species. USDA/APHIS is assisting with research and development of the product and the registration process. However, the registrant of the product will be the manufacturer.

As you indicate, the use of a large bait pellet may be a good choice for controlling rats and reducing the impacts on birds. However, this may not be the best option in all locations for all products. In areas where nontarget mammals are a concern, this may be a poor choice. Hawaii (and other island ecosystems) is an exception because there are no

native mammals on the islands. For rangeland use of zinc phosphide, chlorophacinone or diphacinone, this approach would be impractical and dangerous to nontarget species.

Comments are made in the 10/01 Draft indicating the use of bait stations would eliminate the risk to nontarget species. We agree that using bait stations can eliminate some nontarget hazards and reduce exposure in the environment. However, in rangeland situations or noncrop environments where access is prohibitive, bait stations are not a practical option.

**EFED response:** EFED notes that the USGS, not APHIS, is experimenting with a 6-g bait. The 6-g bait was mentioned only as an example of a mitigation technique used in one specific situation, not as a recommendation that all rodenticide baits be this size. Because this addresses mitigation (i.e., a potential means of reducing exposure), the statement has been deleted from the assessment. Mitigation measures will be addressed in a later phase of the reregistration process.

8) **Comment:** When considering using rodenticides, the cost and benefits the action must be carefully considered. The 10/01 Draft is heavily weighted towards the negative impacts of brodifacoum. However, in certain situations, the use brodifacoum may be less of a long-term impact than the use of other control measures or no control at all. For example, the use of rodenticides has been shown to be very effective for increasing avian nesting activity on off-shore islands. The Pacific island of Midway is a perfect example. Following rat eradication efforts employing anticoagulant rodenticides, the population of boobies and other seabirds has exploded. The USFWS now hails this as one of their flag ship achievements. The use of brodifacoum provided a quick control method, but presented short-term risk to nontarget species. However, it resulted in enormous benefits to the conservation of seabirds. Other products or control measures may not have achieve such dramatic results is such a short time with so little risk.

**EFED response:** The Agency will be considering benefits later in the reregistration process, and the document has been modified to clarify that this is EFED's assessment of potential risks. The number of studies and incidents reports on brodifacoum merely reflect the information available the present time.

9) **Comment:** Over the years the EPA consistently states that zinc phosphide is the safest rodenticide. Yet the 10/01 Draft contradicts this statement by showing zinc phosphide to have little potential for secondary hazard, but a high potential for primary hazards. The overall conclusion of this assessment ranks zinc phosphide products 5$^{th}$ out of the 11 formulations evaluated. EPA should be consistent when discussing the merits of products.

**EFED response:** EFED disagrees with the statement that zinc phosphide is "safe". No pesticide, and certainly not one formulated to be lethal to mammals, should be considered safe to nontarget organisms. APHIS/TZPC provided no documentation that EPA has ever determined

that zinc phosphide is "safe". The current assessment does not contradict any previous risk assessments for zinc phosphide. Previously, the Agency has made "reduced-risk" determinations for zinc phosphide when compared to other field rodenticides (e.g., strychnine, 1080) previously registered for field use. However, even if zinc phosphide poses less potential risk than some other rodenticides, it still does pose potential risks.